the extent permitted under part 20 of this chapter, and in accordance with §20.63 of this chapter, information contained in such records that would identify patient or research subjects shall not be available for public disclosure except as provided in those parts.

(c) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002]

§821.60 Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.

PART 822—POSTMARKET SURVEILLANCE

Subpart A—General Provisions

Subpart B—Notification

Subpart C—Postmarket Surveillance Plan

Subpart D—FDA Review and Action

Subpart E—Responsibilities of Manufacturers

Subpart F—Waivers and Exemptions

AUTHORITY: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

SOURCE: 67 FR 38887, June 6, 2002, unless otherwise noted.

Subpart A—General Provisions

§ 822.1 What does this part cover?

This part implements section 522 of the Federal Food, Drug, and Cosmetic Act by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:

(a) Failure of the device would be reasonably likely to have serious adverse health consequences;

(b) The device is intended to be implanted in the human body for more than 1 year;

(c) The device is intended to be used outside a user facility to support or sustain life. If you fail to comply with requirements that we order under section 522 of the Federal Food, Drug, and Cosmetic Act and this part, your device is considered misbranded under section 502(t)(3) of the Federal Food, Drug, and Cosmetic Act and you are in violation of section 301(q)(1)(C) of the Federal Food, Drug, and Cosmetic Act; or

(d) The device is expected to have significant use in pediatric populations.

[67 FR 38887, June 6, 2002, as amended at 88 FR 16880, Mar. 21, 2023]

§ 822.2 What is the purpose of this part?

The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

§ 822.3 How do you define the terms used in this part?

Some of the terms we use in this part are specific to postmarket surveillance and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation of the law. This section of the part defines the following terms:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, as amended.

(b) *Designated person* means the individual who conducts or supervises the conduct of your postmarket surveillance. If your postmarket surveillance plan includes a team of investigators, as defined below, the designated person is the responsible leader of that team.

(c) *Device failure* means a device does not perform or function as intended, and includes any deviation from the device's performance specifications or intended use.

(d) *General plan guidance* means agency guidance that provides information about the requirement to conduct postmarket surveillance, the submission of a plan to us for approval, the content of the submission, and the conduct and reporting requirements of the surveillance.

(e) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in §1271.3(d) of this chapter that does not meet the criteria in §1271.10(a) and that is also regulated as a device.

(f) *Investigator* means an individual who collects data or information in support of a postmarket surveillance plan.

(g) *Life-supporting or life-sustaining device used outside a device user facility* means that a device is essential to, or

yields information essential to, the restoration or continuation of a bodily function important to the continuation of human life and is used outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. A physician's office is not a device user facility.

(h) *Manufacturer* means any person, including any importer, repacker, and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, processes a device, or engages in any of the activities described in § 807.3(d) of this chapter.

(i) *Postmarket surveillance* means the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device.

(j) *Prospective surveillance* means that the subjects are identified at the beginning of the surveillance and data or other information will be collected from that time forward (as opposed to retrospective surveillance).

(k) *Serious adverse health consequences* means any significant adverse experience related to a device, including device-related events that are life-threatening or that involve permanent or long-term injuries or illnesses.

(l) *Specific guidance* means guidance that provides information regarding postmarket surveillance for specific types or categories of devices or specific postmarket surveillance issues. This type of guidance may be used to supplement general guidance and may address such topics as the type of surveillance approach that is appropriate for the device and the postmarket surveillance question, sample size, or specific reporting requirements.

(m) *Surveillance question* means the issue or issues to be addressed by the postmarket surveillance.

(n) *Unforeseen adverse event* means any serious adverse health consequence that either is not addressed in the labeling of the device or occurs at a rate higher than anticipated.

(o) *Unique device identifier (UDI)* means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A UDI is composed of:

(1) A *device identifier*—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and

(2) A *production identifier*—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(i) The lot or batch within which a device was manufactured;

(ii) The serial number of a specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

[67 FR 38887, June 6, 2002, as amended at 78 FR 58823, Sept. 24, 2013]

§ 822.4 Does this part apply to me?

If we have ordered you to conduct postmarket surveillance of a medical device under section 522 of the Federal Food, Drug, and Cosmetic Act, this part applies to you. We have the authority to order postmarket surveillance of any class II or class III medical device, including a device reviewed under the licensing provisions of section 351 of the Public Health Service Act, that meets any of the following criteria:

(a) Failure of the device would be reasonably likely to have serious adverse health consequences;

(b) The device is intended to be implanted in the human body for more than 1 year;

(c) The device is intended to be used to support or sustain life and to be used outside a user facility; or

(d) The device is expected to have significant use in pediatric populations.

[67 FR 38887, June 6, 2002, as amended at 88 FR 16880, Mar. 21, 2023]

Subpart B—Notification

§ 822.5 How will I know if I must conduct postmarket surveillance?

We will send you a letter (the postmarket surveillance order) notifying you of the requirement to conduct postmarket surveillance. Before we send the order, or as part of the order, we may require that you submit information about your device that will allow us better to define the scope of a surveillance order. We will specify the device(s) subject to the surveillance order and the reason that we are requiring postmarket surveillance of the device under section 522 of the act. We will also provide you with any general or specific guidance that is available to help you develop your plan for conducting postmarket surveillance.

§ 822.6 When will you notify me that I am required to conduct postmarket surveillance?

We will notify you as soon as we have determined that postmarket surveillance of your device is necessary, based on the identification of a surveillance question. This may occur during the review of a marketing application for your device, as your device goes to market, or after your device has been marketed for a period of time.

§ 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

(a) If you do not agree with our decision to order postmarket surveillance for a particular device, you may request review of our decision by:

(1) Requesting a meeting with the Director of the Office that issued the order for postmarket surveillance;

(2) Seeking internal review of the order under § 10.75 of this chapter;

(3) Requesting an informal hearing under part 16 of this chapter; or

(4) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site (*http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOmbudsman/default.htm.*).

[67 FR 38887, June 6, 2002, as amended at 72 FR 17399, Apr. 9, 2007; 78 FR 18233, Mar. 26, 2013; 85 FR 18843, Apr. 2, 2020; 88 FR 16880, Mar. 21, 2023]

Subpart C—Postmarket Surveillance Plan

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Biologics Evaluation and Research, send your submission to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002. For devices regulated by the Center for Drug Evaluation and Research, send your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B, Ammendale Rd., Beltsville, MD 20705–1266. For devices regulated by the Center for Devices and Radiological Health, send your submission to the Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993–0002. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.

[87 FR 17950, Mar. 29, 2022]

§ 822.9 What must I include in my submission?

Your submission must include the following:

(a) Organizational/administrative information:

(1) Your name and address;

(2) Generic and trade names of your device;

(3) Name and address of the contact person for the submission;

(4) Premarket application/submission number and device identifiers for your device;

(5) Table of contents identifying the page numbers for each section of the submission;

(6) Description of the device (this may be incorporated by reference to the appropriate premarket application/submission);

(7) Product codes and a list of all relevant model numbers; and

(8) Indications for use and claims for the device;

(b) Postmarket surveillance plan;

(c) Designated person information;

(1) Name, address, and telephone number; and

(2) Experience and qualifications.

[67 FR 38887, June 6, 2002, as amended at 78 FR 58823, Sept. 24, 2013]

§ 822.10 What must I include in my surveillance plan?

Your surveillance plan must include a discussion of:

(a) The plan objective(s) addressing the surveillance question(s) identified in our order;

(b) The subject of the study, e.g., patients, the device, animals;

(c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;

(d) The surveillance approach or methodology to be used;

(e) Sample size and units of observation;

(f) The investigator agreement, if applicable;

(g) Sources of data, e.g., hospital records;

(h) The data collection plan and forms;

(i) The consent document, if applicable;

(j) Institutional Review Board information, if applicable;

(k) The patient followup plan, if applicable;

(l) The procedures for monitoring conduct and progress of the surveillance;

(m) An estimate of the duration of surveillance;

(n) All data analyses and statistical tests planned;

(o) The content and timing of reports.

§ 822.11 What should I consider when designing my plan to conduct postmarket surveillance?

You must design your surveillance to address the postmarket surveillance question identified in the order you received. You should consider what, if any, patient protection measures should be incorporated into your plan. You should also consider the function, operating characteristics, and intended use of your device when designing a surveillance approach.

§ 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?

Guidance documents that discuss our current thinking on preparing a postmarket surveillance submission and designing a postmarket surveillance plan are available on the Center for Devices and Radiological Health's website, the Food and Drug Administration main website, and from the Food and Drug Administration, Center for Devices and Radiological Health, Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. They do not establish legally enforceable rights or responsibilities and do not legally bind you or FDA. You may choose to use an approach other than the one set forth in a guidance document, as long as your alternative approach complies with the relevant statutes (laws) and regulations. If you wish, we will meet with you to discuss whether an alternative approach you are considering will satisfy the requirements of the act and regulations.

[75 FR 20915, Apr. 22, 2010, as amended at 87 FR 17950, Mar. 29, 2022]

§ 822.13 [Reserved]

§ 822.14 May I reference information previously submitted instead of submitting it again?

Yes, you may reference information that you have submitted in premarket submissions as well as other

postmarket surveillance submissions. You must specify the information to be incorporated and the document number and pages where the information is located.

§ 822.15 How long must I conduct postmarket surveillance of my device?

The length of postmarket surveillance will depend on the postmarket surveillance question identified in our order. We may order prospective surveillance for a period up to 36 months; longer periods require your agreement. If we believe that a prospective period of greater than 36 months is necessary to address the surveillance question, and you do not agree, we will use the Medical Devices Dispute Resolution Panel to resolve the matter. You may obtain guidance regarding dispute resolution procedures from the Center for Devices and Radiological Health's (CDRH') Web site (*http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOmbudsman/default.htm.*). The 36-month period refers to the surveillance period, not the length of time from the issuance of the order.

[72 FR 17400, Apr. 9, 2007, as amended at 78 FR 18233, Mar. 26, 2013]

Subpart D—FDA Review and Action

§ 822.16 What will you consider in the review of my submission?

First, we will determine that the submission is administratively complete. Then, in accordance with the law, we must determine whether the designated person has appropriate qualifications and experience to conduct the surveillance and whether the surveillance plan will result in the collection of useful data that will answer the surveillance question.

§ 822.17 How long will your review of my submission take?

We will review your submission within 60 days of receipt.

§ 822.18 How will I be notified of your decision?

We will send you a letter notifying you of our decision and identifying any action you must take.

§ 822.19 What kinds of decisions may you make?

If your plan:	Then we will send you:	And you must:
(a) Should result in the collection of useful data that will address the postmarket surveillance question	An approval order, identifying any specific requirements related to your postmarket surveillance	Conduct postmarket surveillance of your device in accordance with the approved plan
(b) Should result in the collection of useful data that will address the postmarket surveillance question after specific revisions are made or specific information is provided	An approvable letter identifying the specific revisions or information that must be submitted before your plan can be approved	Revise your postmarket surveillance submission to address the concerns in the approvable letter and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit
(c) Does not meet the requirements specified in this part	A letter disapproving your plan and identifying the reasons for disapproval	Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit
(d) Is not likely to result in the collection of useful data that will address the postmarket surveillance question	A letter disapproving your plan and identifying the reasons for disapproval	Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit

§ 822.20 What are the consequences if I fail to submit a postmarket surveillance plan, my plan is disapproved and I fail to submit a new plan, or I fail to conduct surveillance in accordance with my approved plan?

The failure to have an approved postmarket surveillance plan or failure to conduct postmarket surveillance in accordance with the approved plan constitutes failure to comply with section 522 of the act. Your failure would be a prohibited act under section 301(q)(1)(C) of the act, and your device would be misbranded under section 502(t)(3) of the act. We have the authority to initiate actions against products that are adulterated or misbranded, and against persons who commit prohibited acts. Adulterated or misbranded devices can be seized. Persons who commit prohibited acts can be enjoined from committing such acts, required to pay civil money penalties, or prosecuted.

§ 822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?

You must receive our approval in writing before making changes in your plan that will affect the nature or validity of the data collected in accordance with the plan. To obtain our approval, you must submit the request to make the proposed change and revised postmarket surveillance plan to the applicable address listed in § 822.8. You may reference information already submitted in accordance with § 822.14. In your cover letter, you must identify your submission as a supplement and cite the unique document number that we assigned in our acknowledgment letter for your original submission, specifically identify the changes to the plan, and identify the reasons and justification for making the changes. You must report changes in your plan that will not affect the nature or validity of the data collected in accordance with the plan in the next interim report required by your approval order.

[87 FR 17950, Mar. 29, 2022]

§ 822.22 What recourse do I have if I do not agree with your decision?

(a) If you disagree with us about the content of your plan or if we disapprove your plan, or if you believe there is a less burdensome approach that will answer the surveillance question, you may request review of our decision by:

(1) Requesting a meeting with the individual who issued the order for postmarket surveillance;

(2) Seeking internal review of the order under § 10.75 of this chapter;

(3) Requesting an informal hearing under part 16 of this chapter; or

(4) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site.

[67 FR 38887, June 6, 2002, as amended at 72 FR 17400, Apr. 9, 2007; 85 FR 18443, Apr. 2, 2020]

§ 822.23 Is the information in my submission considered confidential?

We consider the content of your submission confidential until we have approved your postmarket surveillance plan. After we have approved your plan, the contents of the original submission and any amendments, supplements, or reports may be disclosed in accordance with the Freedom of Information Act. We will continue to protect trade secret and confidential commercial information after your plan is approved. We will not disclose information identifying individual patients. You may wish to indicate in your submission which information you consider trade secret or confidential commercial.

Subpart E—Responsibilities of Manufacturers

§ 822.24 What are my responsibilities once I am notified that I am required to conduct postmarket surveillance?

You must submit your plan to conduct postmarket surveillance to us within 30 days from receipt of the order

(letter) notifying you that you are required to conduct postmarket surveillance of a device. The manufacturer shall commence surveillance not later than 15 months after the day the order was issued.

[88 FR 16880, Mar. 21, 2023]

§ 822.25 What are my responsibilities after my postmarket surveillance plan has been approved?

After we have approved your plan, you must conduct the postmarket surveillance of your device in accordance with your approved plan. This means that you must ensure that:

(a) Postmarket surveillance is initiated in a timely manner;

(b) The surveillance is conducted with due diligence;

(c) The data identified in the plan is collected;

(d) Any reports required as part of your approved plan are submitted to us in a timely manner; and

(e) Any information that we request prior to your submission of a report or in response to our review of a report is provided in a timely manner.

§ 822.26 If my company changes ownership, what must I do?

You must notify us within 30 days of any change in ownership of your company. Your notification should identify any changes to the name or address of the company, the contact person, or the designated person (as defined in § 822.3(b)). Your obligation to conduct postmarket surveillance will generally transfer to the new owner, unless you and the new owner have both agreed that you will continue to conduct the surveillance. If you will continue to conduct the postmarket surveillance, you still must notify us of the change in ownership.

§ 822.27 If I go out of business, what must I do?

You must notify us within 30 days of the date of your decision to close your business. You should provide the expected date of closure and discuss your plans to complete or terminate postmarket surveillance of your device. You must also identify who will retain the records related to the surveillance (described in subpart G of this part) and where the records will be kept.

§ 822.28 If I stop marketing the device subject to postmarket surveillance, what must I do?

You must continue to conduct postmarket surveillance in accordance with your approved plan even if you no longer market the device. You may request that we allow you to terminate postmarket surveillance or modify your postmarket surveillance because you no longer market the device. We will make these decisions on a case-by-case basis, and you must continue to conduct the postmarket surveillance unless we notify you that you may stop your surveillance study.

Subpart F—Waivers and Exemptions

§ 822.29 May I request a waiver of a specific requirement of this part?

You may request that we waive any specific requirement of this part. You may submit your request, with supporting documentation, separately or as a part of your postmarket surveillance submission to the address in § 822.8.

§ 822.30 May I request exemption from the requirement to conduct postmarket surveillance?

You may request exemption from the requirement to conduct postmarket surveillance for your device or any specific model of that device at any time. You must comply with the requirements of this part unless and until we grant an exemption for your device. Your request for exemption must explain why you believe we should exempt the device or model from postmarket surveillance. You should demonstrate why the surveillance question does not apply to your device or does not need to be answered for the device for which you are requesting exemption. Alternatively, you may provide information that answers the surveillance question for your device, with supporting documentation, to the address in § 822.8.

Subpart G—Records and Reports

§ 822.31 What records am I required to keep?

You must keep copies of:

(a) All correspondence with your investigators or FDA, including required reports;

(b) Signed agreements from each of your investigators, if your surveillance plan uses investigators, stating the commitment to conduct the surveillance in accordance with the approved plan, any applicable FDA regulations, and any conditions of approval for your plan, such as reporting requirements;

(c) Your approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan;

(d) All data collected and analyses conducted in support of your postmarket surveillance plan; and

(e) Any other records that we require to be maintained by regulation or by order, such as copies of signed consent documents, evidence of Institutional Review Board review and approval, etc.

§ 822.32 What records are the investigators in my surveillance plan required to keep?

Your investigator must keep copies of:

(a) All correspondence between investigators, FDA, the manufacturer, and the designated person, including required reports.

(b) The approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan.

(c) All data collected and analyses conducted at that site for postmarket surveillance.

(d) Any other records that we require to be maintained by regulation or by order.

§ 822.33 How long must we keep the records?

You, the designated person, and your investigators must keep all records for a period of 2 years after we have accepted your final report, unless we specify otherwise.

§ 822.34 What must I do with the records if the sponsor of the plan or an investigator in the plan changes?

If the sponsor of the plan or an investigator in the plan changes, you must ensure that all records related to the postmarket surveillance have been transferred to the new sponsor or investigator and notify us within 10 working days of the effective date of the change. You must provide the name, address, and telephone number of the new sponsor or investigator, certify that all records have been transferred, and provide the date of transfer.

§ 822.35 Can you inspect my manufacturing site or other sites involved in my postmarket surveillance plan?

We can review your postmarket surveillance programs during regularly scheduled inspections, inspections initiated to investigate recalls or other similar actions, and inspections initiated specifically to review your postmarket surveillance plan. We may also inspect any other person or site involved in your postmarket surveillance, such as investigators or contractors. Any person authorized to grant access to a facility must permit authorized FDA employees to enter and inspect any facility where the device is held or where records regarding postmarket surveillance are held.

§ 822.36 Can you inspect and copy the records related to my postmarket surveillance plan?

We may, at a reasonable time and in a reasonable manner, inspect and copy any records pertaining to the conduct of postmarket surveillance that are required to be kept by this regulation. You must be able to produce records and information required by this regulation that are in the possession of others under contract with you to conduct the postmarket surveillance. Those who have signed agreements or are under contract with you must also produce the records and information upon our request. This information must be produced within 72 hours of the initiation of the inspection. We generally will redact information pertaining to individual subjects prior to

copying those records, unless there are extenuating circumstances.

§ 822.37 Under what circumstances would you inspect records identifying subjects?

We can inspect and copy records identifying subjects under the same circumstances that we can inspect any records relating to postmarket surveillance. We are likely to be interested in such records if we have reason to believe that required reports have not been submitted, or are incomplete, inaccurate, false, or misleading.

§ 822.38 What reports must I submit to you?

You must submit interim and final reports as specified in your approved postmarket surveillance plan. In addition, we may ask you to submit additional information when we believe that the information is necessary for the protection of the public health and implementation of the act. We will also state the reason or purpose for the request and how we will use the information.

PART 830—UNIQUE DEVICE IDENTIFICATION

Subpart A—General Provisions

Subpart B—Requirements for a Unique Device Identifier

Subpart C—FDA Accreditation of an Issuing Agency

Subpart D—FDA as an Issuing Agency

Subpart E—Global Unique Device Identification Database

AUTHORITY: 21 U.S.C. 321, 331, 352, 353, 360, 360d, 360i, 360j, 371.

SOURCE: 78 FR 58823, Sept. 24, 2013, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 78 FR 58825, Sept. 24, 2013, unless otherwise noted.

§ 830.3 Definitions.

As used in this part:

Automatic identification and data capture (AIDC) means any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process.

Center Director means the Director of the Center for Devices and Radiological Health or the Director of the Center for Biologics Evaluation and Research, depending on which Center has been assigned lead responsibility for the device.

Device package means a package that contains a fixed quantity of a particular version or model of a device.

Expiration date means the date by which the label of a device states the device must or should be used.

FDA, we, or *us* means the Food and Drug Administration.